The FDA Says Lobelia Can "Temporarily Reduce[] Your Desire to Smoke"

Schneider et al. (United States Letters Patent No. 5,414,005) ("Schneider"), at column 3, lines 5-9, said (in 1994), lobelia "OTC products, as with other OTC products, have been subjected to FDA action questioning the efficacy of the formulation. It was believed that effective doses of lobeline could not be obtained without an invasive dosage form, such as injection."

The 1994 "FDA action" did not find lobeline useless; it simply questioned the proper regulatory classification of lobeline, for FDA regulatory purposes. The end result of this FDA action was the promulgation by the Commissioner of the Food & Drug Administration, on October 26, 1999, of regulations (now codified at 21 C.F.R. Part 101) clarifying that lobelia is properly classified as a "nutritional supplement." The current regulations say that as such, lobelia may now lawfully be described as a "smoking alternative," that "temporarily reduces your desire to smoke" and "mimics the oral sensation of cigarette smoke." Thus, the FDA does not find lobelia "useless": to the contrary, the FDA expressly says lobelia can be labeled, "temporarily reduces your desire to smoke."

This regulatory outcome is not surprising. It is supported by the weight of scientific authority in the field. In fact, Schneider itself discloses clinical data supporting this.

Schneider Proves Lobelia Is "Useful"

Schneider provides ample data showing lobelia has utility for the claimed use. The United States Patent Office reviewed this data, concluding that it proves utility for lobelia. This data is included in two Declarations Schneider submitted during prosecution, presenting clinical evidence of lobelia's usefulness.

Schneider says that in a double-blind study, "an effective amount is approximately 30-90 mg L-lobeline sulfate administered sublingually per day." Schneider Declaration at 4 (29 Aug. 1994). Schneider says, "The results suggesting a reduction of cigarettes smoked, from well over 200, down to one to 13, with respect to high doses of lobeline, is striking." Schneider Second Declaration at 6, ¶ 11 (Oct. 28, 1994). Schneider summarizes, "The difference between the placebo and the lobeline group became greater as compliance to therapy increased, again indicating that lobeline reduces tobacco withdrawal symptoms. The

results of figure 1 are striking in demonstrating a reduction in smoking withdrawal symptoms." Id. at 8.

The U.S. Patent Office reviewed this clinical data. The Patent Office found this data proves that lobelia has "utility" sufficient to overcome a § 101 rejection.

APPLICANT'S STATED UTILITY IS LEGALLY SUFFICIENT

Claims 1-20 stand rejected because "there is no evidence that the combined use of educational materials, hypnosis and the recited natural substances produces a therapeutically effective method for reducing or eliminating a craving form smoking. There is no clinical evidence that the combined effects will produce the claimed result." Examiner requires "clinical evidence" to support the claimed utility. Applicant respectfully requests that this objection be withdrawn, because it demands a level of evidentiary support not required by the law nor the Manual of Patent Examining Procedure.

Utility Objections are Rarely Sustained

Rejections under 35 U.S.C. 101 have rarely been sustained by the Federal courts. Manual of Patent Examining Procedure § 2107 ¶II; § 2107 ¶III.B. (Feb. 2000). Thus, "situations where an invention is found to be inoperable and therefore lacking utility are rare, and rejections

maintained solely on this ground by a Federal court even rarer." Id. Thus, where the applicant sets forth a specific utility, courts are reluctant to uphold a rejection under 35 U.S.C. 101 solely on the basis that the applicant's opinion as to the nature of the specific utility is inaccurate. Manual of Patent Examining Procedure § 2107 ¶I.

Here, applicant has set forth a specific utility. While the Examiner may believe that applicant's opinion regarding utility is inaccurate, that is not an allowable basis to reject the claims. A utility rejection is sustainable only where it meets two tests: a facts-based test, and a logic-based test. Here, the rejection does not meet either test.

The Claimed Utility Is Not "Wholly Inconsistent" With contemporary Knowledge

A § 101 rejection must meet a fact-based test: rejection is appropriate only where (1) the applicant fails to disclose any utility at all for the invention, or (2) if the utility can "only be true if it violated a scientific principle, such as the second law of thermodynamics, or a law of nature, or [is] wholly inconsistent with contemporary knowledge in the art." In re Gazave, 379 F.2d 973, 978 (C.C.P.A. 1967).

Here, applicant (1) discloses a utility (a combination of elements synergistic for anti-smoking), and (2) this utility does not violate a law of nature and is not "wholly inconsistent" with contemporary knowledge in the art. To the contrary, the utility is in large part consistent with contemporary knowledge in the art.

It is known in the art that each of these three individual elements has been investigated for anti-smoking utility. See Specification at page 1, lines 10-16. Applicant has found that using the three elements together provides results synergistic, or unexpectedly good, compared to the results seen for any one component. Thus, applicant's asserted usefulness, while unexpected, is not "wholly inconsistent" with contemporary knowledge.

The Claimed Utility Is Not Illogical

Where an applicant has specifically asserted that an invention has particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong," even if there is reason to believe that the assertion is not entirely accurate. Manual of Patent Examining Procedure §2107.01 ¶III.B (Feb. 2000). Rather, Office personnel must determine if (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion

is based are inconsistent with the logic underlying the assertion. Id.

Here, there is no allegation that (A) applicant's logic is flawed, nor (B) that the facts are inconsistent with the logic. Thus, the rejection is not sustainable under the logic test.

The rejection is based on a belief that the applicant's facts (not applicant's logic) are inaccurate. This kind of rejection is not allowable. See Manual of Patent Examining Procedure § 2107 ¶ I.

Summary - § 101

The § 101 rejection is based on out-of-date information on FDA regulations, and an apparently incomplete copy of the Schneider reference (without the accompanying prosecution history). Given the additional information discusses here, Applicant respectfully requests that the §101 rejection be withdrawn.

CLAIM REJECTIONS - 35 U.S.C. § 112

Claims 1-20 stand rejected under 35 U.S.C. §112, ¶1, as encompassing subject matter not enabled by the specification, because "the disclosure does not reveal what this amount actually is." Applicant respectfully requests that this rejection be withdrawn, because (A) the

specification is fully enabling in light of the teachings of the prior art, and (B) when the § 101 rejection is withdrawn, the accompanying § 112, ¶1 rejection must also be withdrawn.

THE SPECIFICATION IS FULLY ENABLING IN LIGHT OF THE TEACHINGS OF THE PRIOR ART.

An "Effective Amount" of Lobeline is Known in the Art

Claim 1 and 11 require "lobelia in an amount effective…." The prior art teaches that an "effective amount" of lobeline is 0.6 to 10 mg per day, depending on such factors as the severity of the user's prior nicotine usage, the lobelia administration route, and the user's physical size. This level of knowledge in the art is proven by Schneider. Schneider proves this in two ways: describing Schneider's own product, and describing other, prior art products.

Schneider says "lobeline is administered in an amount equivalent to 0.6 to 7.5 mg of lobeline free base. This amount of lobeline provides an effective level of lobeline through the sublingual mucosa to alleviate nicotine withdrawal symptoms." Schneider at col. 4, lines 15-20. Schneider discloses using tablets comprising 2.5 mg L-lobeline sulfate, 5.0 mg L-lobeline sulfate and 7.5 mg L-

lobeline sulfate. Schneider Declaration at 2 (29 Aug. 1994). Schneider says that, in Schneider's double-blind study, "an effective amount is approximately 30-90 mg L-lobeline sulfate administered sublingually per day." Schneider Declaration at 4 (29 Aug. 1994).

Regarding others' prior-art lobeline formulations, Schneider notes, "The directions with [OTC pharmaceutical] lobeline products recommend a daily dose of up to 6 milligrams," id. at col. 2, lines 39-40, and "there have been reports of using lobeline in oral formulations at doses in excess of 10 mg/day," id. at col. 2, lines 45-46. This is confirmed in, for example, Hart, United Kingdom Letters Patent No. 1,017,032 at col. 1, lines 32-39 ("It is well known to provide anti-smoking tablets containing lobeline . . . . They commonly contain about 2 mg. of lobeline sulphate and are taken one to three times per day to supply the user with about 6 mg. of lobeline sulphate daily.").

The prior art thus teaches what is an "effective amount" of lobeline. Thus, applicant need not expressly reiterate this. That is because the Court of Appeals for the Federal Circuit recently held, "interpretation of what is disclosed must be made in light of the knowledge of one skilled in the art." Atmel Corp. v. Information Storage Devices, Inc., (slip op. 99-1082) (Fed. Cir., Dec. 28,

1999). In other words, § 112 is satisfied "if the patent applicant sets forth in the written description what one skilled in the art would need to know to make and use the claimed invention." See id. Here, because the art teaches what is an "effective amount" of lobeline, applicant need not expressly reiterate it. Thus, applicant requests the rejection be withdrawn as to claims 1 and 11.

"Weight Control Products" Are Known In The Art

Dependent claims 7-9 and 17-19 recite, as an additional element, a "weight-control product." These claims stand rejected because the disclosure "does not reveal the therapeutically effective dosage amounts for any of the substances disclosed."

Applicant respectfully requests that this rejection be withdrawn, as weight control products (such as stimulants like caffeine (coffee, tea, guarana) and ephedrine (ma huang)), are widely known in the art, as are therapeutically-effective amounts of them.

The Other Recited Constituents Are Known In The Art

Dependent claims 2-8, 10, 12-16 and 20 recite various additional ingredients. These claims stand rejected because the disclosure "does not reveal the therapeutically

effective dosage amounts for any of the substances disclosed." These claims do not, however, require a "therapeutically effective" dosage amount for these additional ingredients. That limitation is not part of the claims. Thus, applicant respectfully requests the rejection be withdrawn as to these claims.

THE § 112 REJECTION MUST BE WITHDRAWN IF THE § 101 REJECTION IS WITHDRAWN

"A 35 U.S.C. 112, first paragraph, rejection should not be imposed or maintained unless an appropriate basis exists for imposing a rejection under 35 U.S.C. 101. . . . In particular, the factual showing needed to impose a rejection under 35 U.S.C. 101 must be provided if a rejection under 35 U.S.C. 112, first paragraph, is to be imposed." MPEP §2107 ¶ IV (Feb. 2000).

Here, as discussed above, applicant believes that the §101 rejection must be withdrawn. Thus, applicant respectfully requests the accompanying §112, ¶1 rejection be withdrawn.

CLAIM REJECTIONS - 35 U.S.C. § 102(B)

Claims 1-20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the inventor's own on-sale products. Accordingly, enclosed is an Affidavit Under Rule 1.131 to "swear behind" the cited art.